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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,327	12/03/2003	John Kirchgeorg	LIFE02WAB	5961

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EXAMINER	
SCHAETZLE, KENNEDY	
ART UNIT	PAPER NUMBER
3766	
MAIL DATE	DELIVERY MODE
06/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/727,327	KIRCHGEORG ET AL.	
	Examiner	Art Unit	
	Kennedy J. Schaetzle	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,14 and 16-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,14 and 16-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 11, 14, 16-21 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andrews et al. (Pat. No. 6,186,977).

Regarding claim 11, Andrews et al. disclose a multi-component emergency medical system 10 comprising: a breathable oxygen delivery system 50; a defibrillation system 65; at least one measurement system 40 which measures at least one of blood or gas content, saturation, affinity or perfusion (see sensors 42 and 43); and a unitary casing 22 for housing said oxygen delivery system, said defibrillation system and said measurement system.

Regarding limitations pertaining to the cumulative size and weight of the unitary casing, oxygen delivery system, defibrillation system, and measurement system, the courts have long recognized that changes in size or proportion are not sufficient to saliently distinguish over prior art inventions merely differing in scale (see *In re Rose*, 220 F. 2d 459, 105 USPQ 237 (CCPA 1955)). The courts have also indicated that the mere act of making a device portable is not sufficient by itself to warrant patentability (see *In re Lindberg*, 194 F. 2d 732, 93 USPQ 23 (CCPA 1952)). *Ex parte Wu*, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989), *In re Larson*, 340 F. 2d 965, 144 USPQ 347 (CCPA 1965) and *In re Kuhle* 526 F. 2d 553, 188 USPQ 7 (CCPA 1975) all relate to decisions where the elimination of a step or element and its function have been considered obvious if the function of the element is not desired. Andrews et al. further teach that the casing 22 should be relatively compact in order to enhance mobility of the system (col. 1, lines 21-32, col. 5, lines 47-58, col. 6, lines 59-67, etc.), and disclose throughout the specification that many different modifications and embodiments of the invention are possible depending on the application and preferences of the designer (see for example the text abridging columns 6 and 7).

Given the general desire and recognized need in emergency medical situations to provide lightweight, portable equipment, and given the various court cases and teachings of Andrews et al. elaborated above, those of ordinary skill in the emergency medical treatment art would have considered it obvious to make the system of a size and weight to allow single hand/hand-held portability. It is the type of emergency and patient most likely to be encountered that would dictate the equipment necessary to be

contained within the casing and thus the relative size and weight of the overall system. All of the systems recited by the applicants are old and well-known in the prior art. With a reasonable expectation of success, one skilled in the art could have combined the elements as claimed with no change in their respective functions, and the combination would have yielded nothing more than predictable results. For all of the above reasons, one of ordinary skill in the art would have at least found it obvious to try making the system of a size and weight which can easily be carried by a single hand or hand-held.

Regarding claim 14, while Andrews et al. does not elaborate on the specific type of defibrillator system used, the examiner takes Official Notice that AEDs are well-known portable and standard emergency equipment (attention is drawn to the applicants' own patent specification col. 1, lines 20-35). Automatic systems are especially useful in high stress emergency situations where operator error may severely affect the survivability of the patient. Said systems aid the caregiver by relieving the burden and responsibility of decision making, and have proven reliability and effectiveness in the field.

Regarding claim 18 and claims with similar limitations, in the very least the communications system 60 represents a prompting system capable of directing a user through a protocol employing the oxygen delivery system and at least one measurement system (see col. 5, lines 59-67) in the same manner that one calling 9-1-1 may get prompts, instructions or assistance from a remote center staffed by personnel with medical training. In any event, such prompting systems are a well-known and desirable technique in the medical arts to aid the rescuer in high stress emergency

situations where human error may lead to disastrous consequences. Such systems are commonplace in emergency treatment devices such as the AED. To implement similar techniques to improve related emergency systems in order to provide the most effective treatment and eliminate operator error would have therefore been considered obvious to those of ordinary skill in the art.

Regarding claim 19 (with similar comments applying to claims 20, 24 and 25), while Andrews et al. do not discuss the use of a control processor for moderating the prompting system to direct the user based on feedback from at least one measurement system, the courts have indicated that the automation of a manual activity to accomplish the same result is not sufficient to distinguish over the prior art (see *In re Venner*, 262 F. 2d 91, 95, 120 USPQ 193, 194 (CCPA 1958)). Here the machine is merely replacing the actions of the physician. For example, a physician or paramedic detecting low blood oxygen level would likely initiate oxygen delivery or other appropriate therapy, or in the very least, direct those with access to the treatment system on the proper procedure for doing so. The applicants' in fact state that such protocols for the coordination of oximetry, oxygen delivery, and defibrillation are known in the medical arts (col. 3, lines 54-57). Furthermore, such prompting systems for emergency equipment in general are old and well-known in the art. Official Notice is taken that AED devices, for example, commonly provide on-screen or voice command instructions (attention is directed to col. 1, lines 20-28, col. 3, lines 44-54 and the text abridging cols. 3 and 4 of the applicants' 497 patent) for proper placement of electrodes, shock procedure, and safety warnings in an effort to lessen the chances for human error in high stress situations. It would be

reasonable to expect similar beneficial and predictable results for other emergency equipment often used in locations remote from primary care centers. To include a prompting system to direct an operator on proper use of the oxygen delivery system based on the results of diagnostic measurements would have therefore been considered a matter of obvious design.

Regarding claims 21 and 26, Andrews et al. disclose that a wide variety of monitors may be incorporated into the system (see for example col. 5, lines 29-47). While the use of a display *per se* is not discussed, those of ordinary skill in the art would have readily understood said monitoring equipment to include displays as is old and well-known in the medical arts. Clearly the use of a display to convey vital information to caregivers on patient condition is crucial to providing adequate and effective treatment. As such, the inclusion of a display system would have been considered blatantly obvious to those of ordinary skill in the medical treatment arts.

4. Claims 22 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andrews et al. in view of Dudley (Pat. No. 3,905,363) or Sundblom et al. (Pat. No. 3,820,566).

Andrews et al. do not discuss means for controlling the oxygen delivery system, for switching or prompting a user to switch said oxygen delivery system between a variable flow rate/pressure cyclic ventilator mode and a fixed flow rate mode. Dudley teaches the importance of utilizing separate ventilator modes of operation depending on the patient's needs, where one mode intrinsically involves variable flow rates to assist the patient's breathing based on demand and the other mode involves

fixed flow rates without feedback to completely control the intake of fluid when a patient is not breathing (see for example cols. 1 and 2). Since the ability to provide for different modes of operation to account for the patient's condition is a decided advantage and well-known in the art, those of ordinary skill looking to enhance the versatility and thus the effectiveness of treatment, would have considered incorporation of the means for modal control into the system of Andrews et al. to be obvious.

Sundblom et al. disclose a versatile, compact ventilator and teach that prior to their invention, users had little, if any, opportunity to adjust flow rates --flow rates were essentially always fixed (see col. 1, lines 26-43). Sundblom et al. also teach in the same section that because it is desirable to have a large initial flow at the beginning of the inspiratory phase with diminished flow towards the end of the phase, the ability to provide variable flow rates is advantageous. As stated in the text abridging columns 2 and 3, flow and pressure can be automatically adjusted or manually set. Given the recognized need to enable various flow/pressure modes depending on the particular situation at hand and given the disclosure that such control affords the user a versatile and effective way to treat the patient, those of ordinary skill in the art would have seen the obviousness of incorporating flow rate/pressure modal control into the system of Andrews et al..

Reissue Applications

5. The applicants are reminded that any amendment in response to this rejection must be accompanied by a supplemental oath/declaration.

Response to Arguments

6. Applicant's arguments filed April 8, 2008 have been fully considered but they are not persuasive.

The applicants argue that the examiner has repeatedly made assertions in the present tense that the invention would be obvious now as opposed to over ten years ago when the invention was filed. The examiner's use of the phrase, "...would have considered it obvious," (past tense) as opposed to a phrase such as, "...would consider it obvious," (present tense), was implicitly meant to refer to the time of the invention and not the present time.

Semantics aside, the applicants suggest that over ten years ago portable defibrillators were much larger and always contained in their own dedicated housing and did not include oxygen delivery systems and patient monitoring devices. It is stated that the Office Action ignores the relevant time period of the invention and that, "...the state of the art in 1998 was 10 years less developed and advanced than the present."

The evidence of record, however, does not support the applicants' assertions. The invention of Andrews et al. was filed in 1997 and clearly shows defibrillation, oxygen delivery, and monitoring apparatus combined in a single system. The applicants have further not disclosed any special defibrillator innovation that would shrink 1998 style defibrillators down to a size asserted to be compatible with the present invention. As the general desire to downsize components while maintaining or even increasing their functionality has long been a design goal prior to 1998, the accusation

that one must use impermissible hindsight in order to arrive at the applicants' invention is not well founded.

The applicants' assertion that selective picking of some but not all of the components of Andrews et al. would completely defeat the purpose of the Andrews et al. invention is also not agreed with. To the contrary, Andrews et al. teach --and those of ordinary skill in the medical treatment arts would have recognized—that the components of the Andrews et al. system can be modified to suit the needs of the patient application at hand (see for example col. 5, line 48 to col. 6, line 67). The examiner also wishes to point out that no where in the previous Office Action did the examiner suggest to eliminate the anesthesia aspect of the Andrews et al. invention. It is not clear why the elimination of various components of the Andrews et al. invention would "completely defeat the whole purpose" of the invention when Andrews et al. explicitly disclose that many modifications and other embodiments of the invention may be employed. Furthermore, use of the term "comprising" in the claim preambles does not limit the present invention to just the elements recited.

Regarding the applicants' argument that Andrews et al. do not disclose a unitary casing for housing the oxygen delivery system, the term "housing" relates to a support for mechanical parts (Merriam-Webster online). The oxygen cylinder is therefore considered to be supported by the casing 22. Furthermore, Andrews et al. discloses that one can optionally use a conventional oxygen generator 55 in place of the bottle 50 (see col. 6, lines 5-20). Element 55 is clearly shown in Fig. 2 to be within the casing 22. In addition, whether the oxygen bottle was placed outside of the casing or inside of the

casing would have been considered a matter of obvious design to those of ordinary skill in the emergency medical system arts. If there were a problem with the cylinder and hoses catching on clothing, doorways, railings, bedposts, furniture, etc., as the applicants suggest on page 14 of the Remarks, then common sense would suggest to one of ordinary skill that the cylinder and hoses might be placed within the casing (or the casing extended to enclose the oxygen cylinder and associated hoses/valves) to avoid problems of snagging.

The applicant further argues that the applications mentioned in col. 6, lines 59-67 to support the contention that one of ordinary skill would have been motivated towards compact design, are all relatively stationary locations and not even near the size and weight that can be carried by a single hand. The examiner disagrees. Compact design is crucial to military or commercial airlines applications where excess weight and size can have very detrimental consequences. It would be in the very least obvious for one of ordinary skill in the art to design an airline or military emergency medical system with the most compact components available in an effort to save space and weight — decided and recognized advantages in both aviation and/or military applications.

Regarding claim 18 and the recitation of a prompting system, claim 18 does not invoke 112, 6th paragraph and therefore is not limited to specific disclosed embodiments and their equivalents. A phone by the mere act of ringing is a prompting system because the sound prompts one to answer the phone. A phone is also capable of directing a user through a protocol employing oxygen and measurement systems. The applicants' prompting system may be as simple as an age-old set of written instructions

for the user (in much the same manner that airlines include written instructions in the back compartment of a seat instructing the passenger on how to use the emergency oxygen system or seat floatation device, etc.). To include a prompting system to aid the user in correctly operating the emergency medical system, thus increasing the likelihood that the treatment will be successful, would have therefore been considered a matter of common sense by those of ordinary skill in the art.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy J. Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on M-F at 571 272-4949. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kennedy J. Schaetzle/
Primary Examiner, Art Unit 3766

KJS
June 9, 2008